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09/606,314	06/29/2000	Richard Fike	IVGN 174.1 DIV	1340

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/606,314	FIKE ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27,36,92-95,103,110,111 and 122* is/are pending in the application.

4a) Of the above claim(s) *110* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27,36,92-95,103,111 and 122* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/11/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on January 11, 2008 with the cancellation of Claims 112-121, and the addition of newly added Claim 122. Applicant indicates that Claims 27, 36, 92-95, 111 and 122 are pending in the instant application without mentioning previously presented Claim 103 and previously presented but withdrawn Claim 110. Applicant is respectfully reminded of Applicant's election without traverse of the elected species: water as the solvent, animal cell as the cell, and proliferation of a eukaryotic cell in vitro in the reply filed on December 20, 2006 and April 19, 2007. With regard to the rejection made under 35 U.S.C. 102 (b) as set forth in the Office action mail dated July 13, 2007, the omission of Claim 103 is an obvious typographical error given that the Examiner addressed the limitations of the subject matter recited in the claim.

The claims have been examined, insofar, as they read on the elected invention.

Election/Restrictions

Claim 110 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 20, 2006 and the reply filed on April 19, 2007

Claims 27, 36, 92-95, 103, 111 and 122 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27, 36,92-95, 103, 111 and 122, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Pebbles (A*) in view of Fassolitis et al. (U), Irvine (B*), and Wolfe (N). Newly applied as necessitated by amendment.

Applicant claims an agglomerated eukaryotic cell culture medium powder prepared by agglomerating a dry powder eukaryotic cell culture medium with a solvent; wherein said agglomerated powder comprising a biological buffer, upon being reconstituted with water, comprises all the necessary nutritive factors for proliferation or cultivation of a eukaryotic cell *in vitro*. Applicant further claims the agglomerated eukaryotic cell culture medium powder of claim 27, wherein said eukaryotic cell culture medium has a pH of between 7.1-7.5 when said medium is reconstituted with a solvent, wherein said solvent is water or serum. Applicant further claims the medium powder of claim 27, wherein said medium powder exhibits reduced dusting in comparison to a medium powder that is non-agglomerated; wherein said medium powder exhibits more rapid dissolution in comparison to a medium powder that is non-agglomerated; wherein said medium powder exhibits reduced dusting and more rapid dissolution in comparison to a medium powder that is non-agglomerated. Applicant further claims the medium

powder of any one of claims 92-94, wherein the non-agglomerated medium powder is a lyophilized or ball-milled powder. Applicant further claims the agglomerated eukaryotic cell culture medium powder of claim 27, wherein said solvent is water, serum, aqueous acid or base. Applicant further claims the agglomerated eukaryotic cell culture medium powder of claim 27, wherein said eukaryotic cell is an animal cell; and wherein the biological buffer is N-2-hydroxethylpiperazine-N'-2-ethanesulfonic acid.

Peebles teaches a method of obtaining a dried milk powder, which comprises lactose and milk protein, by agglomerating a spray-dried powder with water vapor and droplets of moisture. *See* Column 2, lines 13-70. The particulate matter of the dried milk powder taught by Peebles is of a size substantially greater than the particle size of the original powder, is readily dispersible in water, and has reduced dusting. *See* claims and Column 9, lines 46-54. With regard to the claim limitation "wherein said agglomerated powder upon being reconstituted with water supports the proliferation or cultivation of a eukaryotic cell *in vitro*" of Claim 27, as evidenced by the teachings Fassolitis the prior art agglomerated dry powder taught by Peebles is considered as an agglomerated eukaryotic cell culture medium powder that is able to support the proliferation or cultivation of a eukaryotic cell *in vitro* upon reconstituted with water and inherently having the claim-designated pH range. For example, Fassolitis teaches a method for the cultivation and/or growth of eukaryotic cells, *i.e.*, epithelial cells or "animal cells" using a powdered nonfat dry skim milk filtrate (NDMF) as an eukaryotic cell culture medium. *See* page 201, Column 1, under "Preparation of milk fraction", wherein Fassolitis teaches a method of making NDMF comprising reconstituting a dry

milk powder. On page 200, Column 2, under "Cell culture medium", Fassolitis teaches a cell culture medium supplemented with 5% NDMF and HEPES, wherein the pH of the medium was adjusted to 6.8 to 7.4 that is used to propagate epithelial cells (*see* Table 1 on page 201).

The teachings of Pebbles are set forth above. Pebbles teaches the instantly claimed product except for comprising a biological buffer. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredient to the agglomerated eukaryotic cell culture medium powder taught by Pebbles to provide the instantly claimed invention because at the time the invention was made Fassolitis beneficially taught a cell culture medium supplemented with NDMF and HEPES having a pH of 6.8-7.4 was useful for growing eukaryotic cells; Irvine taught that the pH of water-reconstituted spray-dried milk products could be manipulated by the addition of biological buffers during the spray-drying process and Wolfe taught that biological buffers were known to be beneficial in the making of eukaryotic cell culture medium powders for the proliferation or cultivation of eukaryotic cell lines *in vitro*. For instance, Wolfe teaches a chemically defined basal nutrient medium used for serum-free culture or supplemented with low levels of serum for high and low density culture. The cell culture medium powder taught by Wolfe also comprises a biological buffer, *e.g.,* alpha-glycerolphosphate or N-2-hydroxethylpiperazine-N'-2-ethanesulfonic acid (HEPES). See page 1, lines 46-49. At the time the invention was made, one of ordinary skill in the art would have been motivated and would have had a reasonably expectation of success to add a biological buffer to the agglomerated powder taught by Pebbles to

provide the instantly claimed invention because at the time the invention was made because Irvine taught that the pH of water-reconstituted powdered milk products could be easily affected by the addition of buffers; and, Wolfe taught that in addition to necessary nutrients and protein factors, eukaryotic cell culture media must include a biocompatible buffer as a means of controlling control pH levels, and that the buffering capacity of conventional bicarbonate/carbon dioxide buffering systems can expanded by the inclusion of biocompatible organic buffers, such as the instantly claimed HEPES buffer; and Fassolitis taught that NDMF-supplemented media containing HEPES was useful for the propagating and cultivating eukaryotic cells when the pH of the media was within a biophysiological range. Given the foregoing, the instantly claimed composition would have been no more than a matter of routine optimization to provide a result-effect variable for the making of an agglomerated eukaryotic cell culture medium comprising beneficial nutrients, buffering system and beneficial functional properties, wherein the addition of a biological buffer would provide a convenience for those interested in the proliferation or cultivation of eukaryotic cells *in vitro* without a need for adjusting the pH of the culture medium upon reconstitution with water, especially since Fassolitis taught the utility of powdered milk products in the culturing of eukaryotic cells.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence the contrary.

Claims 27, 36,92-95, 103, 111 and 122, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Getler et al. (AB4, WO 95/00031) n view of Fassolitis et al. (U), Irvine (B*), and Wolfe (N). Newly applied as necessitated by amendment. Applicant's claimed invention was set forth above.

Getler teaches agglomerated milk products and milk-like products which are mad in a two-stage agglomeration process comprising spray drying a pre-agglomerated concentrated premix by return of fine particles to an atomizer and, in a subsequent step, post-agglomeration by wetting and drying in a fluidized bed. The agglomerated dried products taught by Getler comprise the following ingredients: whey protein concentrates (*see* page 1, lines 11-14); and a fat component mixed with water, vitamins, and with raw materials in powder form, *i.e.*, casein, whey, skim milk, malto dextrine, *etc.* *See* page 1, line 36 to page 7, line 2. In Example 3, Getler teaches an agglomerated powder that exhibits reduced dusting and rapid dissolution. With regard to the claim limitation "wherein said agglomerated powder upon being reconstituted with water supports the proliferation or cultivation of a eukaryotic cell *in vitro*" of Claim 27, as evidenced by the teachings Fassolitis the prior art agglomerated dry powder taught by Getler is considered as an agglomerated eukaryotic cell culture medium powder that is able to support the proliferation or cultivation of a eukaryotic cell *in vitro* upon reconstituted with water and inherently having the claim-designated pH range. For example, Fassolitis teaches a method for the cultivation and/or growth of eukaryotic cells, *i.e.*, epithelial cells or "animal cells" using a powdered nonfat dry skim milk filtrate (NDMF) as an eukaryotic cell culture medium. *See* page 201, Column 1, under

"Preparation of milk fraction", wherein Fassolitis teaches a method of making NDMF comprising reconstituting a dry milk powder. On page 200, Column 2, under "Cell culture medium", Fassolitis teaches a cell culture medium supplemented with 5% NDMF and HEPES, wherein the pH of the medium was adjusted to 6.8 to 7.4 that is used to propagate epithelial cells (*see* Table 1 on page 201).

The teachings of Getler are set forth above. Getler teaches the instantly claimed product except for comprising a biological buffer. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredient to the agglomerated eukaryotic cell culture medium powder taught by Getler to provide the instantly claimed invention because at the time the invention was made Fassolitis beneficially taught a cell culture medium supplemented with NDMF and HEPES having a pH of 6.8-7.4 was useful for growing eukaryotic cells; Irvine taught that the pH of water-reconstituted spray-dried milk products could be manipulated by the addition of biological buffers during the spray-drying process and Wolfe taught that biological buffers were known to be beneficial in the making of eukaryotic cell culture medium powders for the proliferation or cultivation of eukaryotic cell lines *in vitro*. For instance, Wolfe teaches a chemically defined basal nutrient medium used for serum-free culture or supplemented with low levels of serum for high and low density culture. The cell culture medium powder taught by Wolfe also comprises a biological buffer, *e.g.,* alpha-glycerolphosphate or N-2-hydroxethylpiperazine-N'-2-ethanesulfonic acid (HEPES). See page 1, lines 46-49. At the time the invention was made, one of ordinary skill in the art would have been motivated and would have had a reasonably expectation of

success to add a biological buffer to the agglomerated powder taught by Getler to provide the instantly claimed invention because at the time the invention was made because Irvine taught that the pH of water-reconstituted powdered milk products could be easily affected by the addition of buffers; and, Wolfe taught that in addition to necessary nutrients and protein factors, eukaryotic cell culture media must include a biocompatible buffer as a means of controlling control pH levels, and that the buffering capacity of conventional bicarbonate/carbon dioxide buffering systems can expanded by the inclusion of biocompatible organic buffers, such as the instantly claimed HEPES buffer; and Fassolitis taught that NDMF-supplemented media containing HEPES was useful for the propagating and cultivating eukaryotic cells when the pH of the media was within a biophysiological range. Given the foregoing, the instantly claimed composition would have been no more than a matter of routine optimization to provide a result-effect variable for the making of an agglomerated eukaryotic cell culture medium comprising beneficial nutrients, a buffering system and beneficial functional properties and effects, wherein the addition of a biological buffer would provide a convenience for those interested in the proliferation or cultivation of eukaryotic cells in vitro without a need for adjusting the pH of the culture medium upon reconstitution with water, especially since Fassolitis taught the utility of powdered milk products in the culturing of eukaryotic cells

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
March 29, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655